IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Fisher *et al.*			
Serial No.	:	09/621,781	Examiner	:	Loeb, Bronwen
Filed	:	July 21, 2000	Group Art Unit	:	1636
For	:	NUCLEIC ACIDS COMPRISING REGIONS OF THE RAT PEG-3 PROMOTER THAT DISPLAY ELEVATED EXPRESSION IN HUMAN CANCER CELLS AND USES THEREOF			

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

May 22, 2003
Date of Deposit

Lisa B. Kole
Attorney Name

35,225
PTO Registration No.

Signature

May 22, 2003
Date of Signature

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. §1.56 and §1.97(c)(2), Applicants respectfully request that the references relating to the above-identified application listed herein in reverse chronological alphabetical order be considered and made of record in the U.S. Patent and Trademark Office.

1. International Patent Application No. PCT/US01/23099, filed July 20, 2001, entitled "NUCLEIC ACIDS COMPRISING REGIONS OF THE RAT PEG-3 PROMOTER AND USES THEREOF", published as WO 02/08242 on January 31, 2002, by the Trustees of Columbia University in the City of New York;

2. Hacein-Bey-Abina S *et al.*, 2002, "Sustained Correction of X-Linked Severe Combined Immunodeficiency by ex Vivo Gene Therapy" *N Engl J Med.* 346(16):1185-1193;

3. Liu Y *et al.*, 2002, "In situ adenoviral interleukin 12 gene transfer confers potent and long-lasting cytotoxic immunity in glioma" *Cancer Gene Ther.* 9(1):9-15;

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8. International Patent Application No. PCT/US00/34564, filed December 20, 2000, entitled "PROGRESSIVE ELEVATED GENE-3 (PEG-3) INDUCES AGGRESSIVE CANCER PHENOTYPE AND REGULATES ANGIOGENESIS", published as WO 01/46386 on June 28, 2001, by the Trustees of Columbia University in the City of New York;

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19. Somia and Verma, 2000, "Gene therapy: trials and tribulations" *Nat Rev Genet.* 1(2):91-99;

20. Stiens L R *et al.*, 2000, "Development of serum-free bioreactor production of recombinant human thyroid stimulating hormone receptor" *Biotechnol Prog.* 16(5):703-709;

21. **Su et al., July 13 2000, "Cooperation between AP1 and PEA3 sites within the progression elevated gene-3 (PEG-3) promoter regulate basal and differential expression of PEG-3 during progression of the oncogenic phenotype in transformed rat embryo cells" Oncogene 19(30):3411-3421.**

22. **Su et al., "Defining the regions within the promoter of progression elevated gene-3 responsible for differential expression during transformation progression", abstract submitted to be presented at the 91st Annual Meeting of the American Association for Cancer Research" in April 2000 but, according to e-mail correspondence from inventor Paul Fisher, never published.**

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29. United States Patent No. 6,472,520 by Fisher, for "RAT PEG-3 PROMOTER", filed March 31, 1998 and issued October 29, 2002;

30. United States Patent No. 6,146,877 by Fisher, for "IDENTIFICATION OF THE PROGRESSIVE-ELEVATED GENE-3 AND USES THEREOF", filed March 31, 1997 and issued November 14, 2000;

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32. Olive M *et al.*, 1997, "A Dominant Negative to Activation Protein-1 (AP1) That Abolishes DNA Binding and Inhibits Oncogenesis" *The Journal of Biological Chemistry*, 272(30):18586-18594;

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34. De Cesare D *et al.*, 1996, "Functional characterization of COM, a DNA region required for cooperation between AP-1 sites in urokinase gene transcription" *Oncogene* 13:2551-2562;

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66. Fisher P B *et al.*, 1979, "Phenotypic Properties and Tumor Promoter-induced Alterations in Rat Embryo Cells Transformed by Adenovirus" *Cancer Research* 39:3051-3057; and

67. Fisher P B *et al.*, 1978, "Interactions between adenovirus, a tumor promoter, and chemical carcinogens in transformation of rat embryo cell cultures" *Proc. Natl. Acad. Sci. USA* 75(5):2311-2314.

The Examiner's attention is particularly invited to references 21 and 22, which are in bold-face text. The referenced citations are listed in the accompanying PTO Form 1449. Copies of the references are submitted herewith in two bound volumes. A copy of the Search

Report received by Applicants in connection with International Application No. PCT/US01/23099 is also enclosed herewith.

Identification of the references listed in the attached PTO Form 1449 is not to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the above-identified application.

Applicants enclose herewith the fee required under 37 C.F.R. §1.17(p). Any required fees not otherwise enclosed herewith may be charged to Deposit Account No. 02-4377. Two copies of this page are enclosed.

Respectfully submitted,

May 22, 2003

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Enclosures
Form PTO-1449
Copies of cited documents

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A34690 (070050.1714)	Serial No. 09/621,781
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant Fisher, *et al.*	
	Filing Date July 21, 2000	Group 1636

U.S. PATENT DOCUMENTS

*Exam. Init.			Document No.								Date	Name	Class	Subclass	Filing Date if Appro.
		29	6	4	7	2	5	2	0		10/29/2002	Fisher			3/31/1998
		30	6	1	4	6	8	7	7		11/14/2000	Fisher			3/31/1997

FOREIGN PATENT DOCUMENTS

			Document No.	Date	Country	Class	Subclass	Translation Yes	Translation No
		1	WO 02/08242	1/31/2002	WIPO				
		8	WO 01/46386	6/28/2001	WIPO				
		24	WO 99/49898	10/9/1999	WIPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

		2	Hacein-Bey-Albina S *et al.*, 2002, "Sustained Correction of X-Linked Severe Combined Immunodeficiency by ex Vivo Gene Therapy" *N Engl J Med.* 346(16): 1185-1193.
		3	Liu Y *et al.*, 2002, "In situ adenoviral interleukin 12 gene transfer confers potent and long-lasting cytotoxic immunity in glioma" *Cancer Gene Ther.* 9(1):9-15.
		4	Losordo D W *et al.*, 2002, "Phase ½ placebo-controlled, double-blind, dose-escalating trial of myocardial vascular endothelial growth factor 2 gene transfer by catheter delivery in patients with chronic myocardial ischemia" *Circulation* 105(17):2012-2018.
		5	Rosen F S, 2002, "Successful Gene Therapy for Severe Combined Immunodeficiency" (Editorial) *N Engl J Med.* 346(16):1241-1243.

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* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		6	Stolberg S G, 2002, "Trials are halted on gene therapy" *New York Times*, page A1, column 3.
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		23	Symes J F, 2000, "Focal angiogenic therapy for myocardial ischemia" *J Card Surg.* 15(4):283-290.
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		56	Gutman A *et al.*, 1990, "The collagenase gene promoter contains a TPA and oncogene-responsive unit encompassing the PEA3 and AP-1 binding sites" *The EMBO Journal* 9(7):2241-2246.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant Fisher, *et al.*	
	Filing Date July 21, 2000	Group 1636

		63	Fisher P B *et al.*, 1982, "Analysis of type 5 adenovirus transformation with a cloned rat embryo cell line (CREF)" *Proc. Natl, Acad. Sci. USA* 79:3527-3531.
		64	Fisher P B *et al.*, 1979, "Tumor Promoters and Epidermal Growth Factor Stimulate Anchorage-Independent Growth of Adenovirus-Transformed Rat Embryo Cells" *Cell* 18:695-705.
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